Health Advisory:

Disease Cluster Associated with Exposure to a Dietary Supplement

March 28, 2008

This document will be updated as new information becomes available. The current version can always be viewed at http://www.dhss.mo.gov

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

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Health Advisory
March 28, 2008

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DIRECTOR

SUBJECT: Disease Cluster Associated with Exposure to a Dietary Supplement

Due to this product being sold in Missouri, and the severe consequences that may occur, the Missouri Department of Health and Senior Services (DHSS) would like to alert Local Public Health Agencies (LPHAs) and health care providers so inquiries can be made about use of this dietary supplement.

Summary:

The U.S. Food and Drug Administration is now advising consumers not to purchase or consume **Total Body Formula** dietary supplement in the flavors of Tropical Orange and Peach Nectar, or **Total Body Mega Formula** dietary supplement in the Orange/Tangerine flavor. The liquid dietary supplement products may cause severe adverse reactions, including significant hair loss, muscle cramps, diarrhea, joint pain, and fatigue. (The FDA news release is provided on the next page.)

According to a report from Florida, affected persons reported using Total Body Formula dietary supplement in February. Hair loss, cramps, nail discoloration, and tongue and lip blisters developed 7-10 days later. This product was distributed to 15 states. Health care providers who see patients with illness possibly related to the use of Total Body Formula products should report these cases to the LPHA, or to DHSS at (800) 392-0272 (24/7). LPHAs who become aware of such cases should contact DHSS' Bureau of Communicable Disease Control and Prevention.

Background:

On March 12, 2008, a local physician's office called the Washington County Health Department (WCHD), Florida, stating they had a patient with severe hair loss, muscle cramps, dark coloration and rings on the nails, and blisters on the tongue and lips. WCHD received another call from a local chiropractor's office who reported seeing patients with the same symptoms. Upon interviewing 23 symptomatic persons, the only common link that could be detected was use of Total Body Formula dietary supplement by Total Body Essential Nutrition, Inc., of Atlanta, Georgia. All ill persons that have been interviewed started taking the implicated batch of the product in February, with symptoms starting 7–10 days later. Once the ill persons stopped taking the dietary supplement, the symptoms improved with the exception of continuing hair loss.

The product was sold at three locations in Chipley, Florida, and each business voluntarily removed it from the shelf. Additionally, this product has been distributed to stores in AL, CA, GA, KY, LA, MI, **MO**, NJ, NC, OH, PA, TN, TX, and VA. FDA was notified of the concern linked to this product and conducted an investigation on March 20. Results are pending. Laboratory analysis results reported from the manufacturer showed higher concentrations of selenium than indicated on the product label. The investigation is ongoing.

Questions should be directed to DHSS' Bureau of Communicable Disease Control and Prevention at 573/751-6113, 866/628-9891, or 800-392-0272.

FDA News

FOR IMMEDIATE RELEASE
March 27, 2008

Media Inquiries:
Stephanie Kwisnek, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Warns Consumers about "Total Body Formula" and "Total Body Mega Formula"

Distributor recalls dietary supplement products after reports of adverse reactions

The U.S. Food and Drug Administration is advising consumers not to purchase or consume Total Body Formula in the flavors of Tropical Orange and Peach Nectar, or Total Body Mega Formula in the Orange/Tangerine flavor. The liquid dietary supplement products may cause severe adverse reactions, including significant hair loss, muscle cramps, diarrhea, joint pain and fatigue.

The Total Body Formula products are sold in eight-ounce and 32-ounce plastic bottles. The Total Body Mega Formula is sold in 32-ounce plastic bottles. Both products are distributed by Total Body Essential Nutrition of Atlanta. The company is the sole distributor of the products and has voluntarily recalled Total Body Formula in the flavors of Tropical Orange and Peach Nectar and Total Body Mega Formula in Orange/Tangerine flavor.

The Florida Department of Health recently provided reports to the FDA on 23 individuals who experienced serious reactions to these products seven to 10 days after ingestion. In all cases, the reactions included significant hair loss, muscle cramps, diarrhea, joint pain and fatigue. The FDA subsequently learned and is investigating a report that some individuals in Tennessee using the same products have experienced similar reactions.

FDA laboratories are analyzing samples of the products to identify the cause of the reactions, including the possibility that the products contain excessive amounts of selenium, which is known to cause symptoms such as those described in the adverse events reported to the agency. Selenium, a trace mineral, is needed only in small amounts for good health.

The products have been distributed in Alabama, California, Florida, Georgia, Kentucky, Louisiana, Michigan, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, Tennessee, Texas and Virginia.

The FDA is advising consumers in all states to avoid using the products immediately and to discard the products by placing them in a trash receptacle outside of the home.

Consumers who have been taking the products and have experienced adverse reactions should consult their health care professional. Consumers and health care professionals can also report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

The FDA is working with the Florida Department of Health in its investigation.

For more information, consumers can call the FDA's toll-free Food Safety Hotline at 1-888-SAFEFOOD.

This document is available on FDA's website at http://www.fda.gov/bbs/topics/NEWS/2008/NEW01812.html.